

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

MEDLINE INDUSTRIES, INC.,)	
)	
Plaintiff,)	
)	
v.)	14 C 3618
)	
C.R. BARD, INC.,)	Judge John Z. Lee
)	
Defendant.)	

MEMORANDUM OPINION AND ORDER

Plaintiff Medline Industries, Inc. (“Medline”) brings this action against Defendant C.R. Bard, Inc. (“Bard”), alleging that Bard infringed three United States patents related to Medline’s Foley-catheter tray. The patents-in-suit are Nos. 8,446,786 (“the ’786 patent”); 8,631,935 (“the ’935 patent”); and 8,678,190 (“the ’190 patent”). The parties seek construction of several terms that appear in the claims of these patents. For the reasons given herein, the Court construes the terms as stated in Appendix I.

Background

The three patents-in-suit relate to a tray for accommodating a catheter assembly and associated materials, including instruments and instructions. The ’786 patent was issued on May 28, 2013; the ’935 patent on January 21, 2014; and the ’190 Patent on March 5, 2014. 2d Am. Compl. ¶¶ 17–19, ECF No. 37. Medline alleges that Bard’s “Bardex I System” and “Bardex II System” infringe these patents.

The parties identified several disputed claim terms in the patents-in-suit. The Court held claim construction hearings on two separate days pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996).

Legal Standard

Claim construction is a question of law to be decided by a judge. *Markman*, 517 U.S. at 391. Claim terms “are generally given their ordinary and customary meaning.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “[T]he ordinary and customary meaning . . . is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). A person having ordinary skill in the art is assumed to read the claim term in the context of the entire patent. *Id.*

“[T]he claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim.” *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002); *see Phillips*, 415 F.3d at 1312. The context in which a term appears in a claim is instructive, and “[b]ecause claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Phillips*, 415 F.3d at 1314. “Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.” *Id.*

Moreover, “[t]he descriptive part of the specification aids in ascertaining the scope and meaning of the claims inasmuch as the words of the claims must be based

on the description. The specification is, thus, the primary basis for construing the claims.” *Id.* at 1315 (quoting *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985)). A particular embodiment described in the specification, however, should not be read into a claim when the claim language is broader than the embodiment. *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). That said, a claim may be limited to its preferred embodiment if permitting expansive claim language would undermine the public notice requirements of 35 U.S.C. § 112. *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005).

In addition, “the prosecution history can often inform the meaning of the claim language.” *Phillips*, 415 F.3d at 1317. For example, it may be used “as support for the construction already discerned from the claim language and confirmed by the written description” in the specification. *800 Adept, Inc. v. Murex Sec., Ltd.*, 539 F.3d 1354, 1365 (Fed. Cir. 2008). Moreover, the prosecution history may serve to “exclude any interpretation that was disclaimed during prosecution.” *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005). However, a claim should not be narrowed “simply by pointing to . . . disclos[ures] in the . . . prosecution history.” *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

Beyond the intrinsic evidence, in some cases, a “court will need to . . . consult extrinsic evidence . . . to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). “In cases where those

subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence.” *Id.* “[E]xperts may be examined to explain terms of art, and the state of the art, at any given time,” but they cannot be used to prove “the proper or legal construction of any instrument of writing.” *Id.*

Analysis

The parties seek construction of the following claim terms: “catheter assembly”; “catheter package assembly”; “instruction manual”; “accessing an instruction manual”; “enclosing printed instructions”; and “a first compartment member having [at least one/an] inclined, stair-step[ped] contour.”

I. “Catheter assembly”

The phrase “catheter assembly” appears in: claims 1, 17, 19, 21, 22, and 25 of the ’935 patent; claims 1, 6, 7, 9–11, 14, 15, and 17 of the ’190 patent; and claim 1 of the ’786 patent. Bard argues that a catheter assembly is “a medical device that includes a catheter connected via tubing to a drainage receptacle.” Def.’s Br. at 3, ECF No. 265. Medline agrees with this definition as a starting point but contends that a person having ordinary skill in the art would understand that the catheter may only be a “Foley” catheter and that the non-catheter tubing component (“tubing component”) must be “coiled.” Pl.’s Br. at 7, ECF No. 278. The parties agree that “catheter assembly” has the same meaning in each of the patents.

A. “Foley” Catheter

Beginning with the claims, the word “Foley” does not appear in any of them. Nor does the word “Foley” appear in the written abstract, background, or “brief

description of the drawings” sections of any of the specifications of the patents-in-suit.

Moreover, each of the patents contain figures that—the parties agree—depict catheter assemblies *without* Foley catheters. This can be seen in Figures 7, 8, and 10 of the ’935 patent.¹ Similarly, Figures 7, 8, 10, and 22 in the ’190 patent present a catheter assembly with no Foley catheter.² This also is true of Figures 7, 8, 10, 22, and 38 in the ’786 patent.

As we shall see, Medline posits that these figures not only do not include a Foley catheter, but that they do not depict any catheter at all as a result of a drafting error. But the Court finds this argument unpersuasive for the reasons I will discuss. And, in any event, the catheter assembly depicted in the figures does appear to include a drainage bag, which is connected to a short piece of tubing, which in turn is connected to a long hollow tube that can only be a catheter.

That said, a Foley catheter does appear as part of a catheter assembly in Figure 14 of the ’190 patent, which is described as an “exemplary panel” of an instruction manual included with the device. ’190 Patent at 16:7–8, 16:25–26. The phrase “Foley Insert Tag” also appears in Figure 11, which is described as a “method 1100 for manufacturing a packaged catheter assembly” *Id.* at 11:28–30. Specifically, in

¹ A catheter assembly is also depicted in Figure 9 in each of the patents, but it is substantially obstructed.

² Obstructed-view illustrations of catheter assemblies are depicted in some other figures.

the third step of the illustration, the method includes “Optionally Plac[ing] Other Objects in Tray (e.g., Foley Insert Tag, Securement Device).”

Additionally, a Foley catheter appears as part of a catheter assembly in Figure 14 of the ’786 patent. Here, too, the specification describes this as an “exemplary panel” of an instruction manual included with the device. ’786 Patent at 20:66. In addition, the phrase “Foley Insert Tag” appears in Figure 11, which is described as a “method 1100 for manufacturing a packaged catheter assembly” *Id.* at 12:12–14. A Foley catheter also appears as part of a catheter assembly in Figures 40 and 41, which are described as illustrative embodiments of printed instructions. *Id.* at 18:28–32. And a Foley catheter is in Figures 15, 16, and 19, which are also described as “exemplary panels” of instructions.

Turning next to the prosecution history, it is undisputed that the proponents of the patents-at-issue made no statements to suggest that the catheter in a catheter assembly must be a “Foley” catheter.

Based upon the intrinsic evidence, the Court finds that a person having ordinary skill in the art would understand that a “catheter assembly” does not require a Foley catheter. The claim language is not so limited. And the occasional disclosures of a Foley catheter in two of the three patents are generally within the context of embodiments of an instruction manual and are only illustrative of possible embodiments.³

³ Bard contends that the following disclosures in the ’786 and ’190 patents are new matter that the Court may not consider in its claim construction: Figure 14; the “Latex Foley Catheter Tray” depicted in Figure 40 of the ’786 patent; the “Foley insertion tag”; and the

The extrinsic evidence is consistent with the intrinsic evidence. The parties' expert witnesses testified at the *Markman* hearing that a "catheter assembly" generally includes a catheter of an *unspecified* type. See *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1331 (Fed. Cir. 2012) (stating that, even when the intrinsic evidence is clear, "[a] district court . . . has the discretion to take expert testimony into account in determining the ordinary meaning of a claim term to one skilled in the art") (citing *Phillips*, 415 F.3d at 1319). Notably, when asked what "catheter assembly" means, Medline's expert Barbara Weintraub stated, "Do you want a Foley catheter? Do you want an intermittent catheter? Do you want an intravascular catheter? What is it you're looking for?" *Markman* Hr'g 1 Tr. ("Hr'g 1 Tr.") at 77, ECF No. 308. Medline's expert Richard Meyst agreed, stating that the phrase "catheter assembly" indicates nothing more than that the assembly involves a catheter and that there are many types of catheters. *Id.* at 110.

And to that point, the expert witnesses testified that there are a variety of types of catheters, including, for example, intravascular, thoracentesis, paracentesis, rectal, and urinary varieties—and that Foley and intermittent catheters are subtypes of urinary catheters. See *id.* at 130–31, 149, 150 (Leinsing); *id.* at 77, 96 (Weintraub).

Notwithstanding this testimony, Medline contends that the term "catheter" in "catheter assembly" must refer to a Foley catheter because, in its view, the only catheters disclosed in the patents are Foleys catheters. As discussed, the Court finds

"Checklist for Foley Catheter Insertion." Def.'s Br. at 7–8 (citing *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1168 (Fed. Cir. 2004)). Regardless of whether this is correct, the added disclosures do not limit a "catheter assembly" to one containing a Foley catheter.

this inconsistent with the intrinsic evidence.⁴ Rather, the Court finds that a person having ordinary skill in the art would understand that only *generic* representations of catheters are disclosed as part of the catheter assemblies in Figures 7, 8, and 10.

For their part, when shown these figures, Medline’s expert witnesses testified that the figures do not include any catheters at all, attributing the absence of catheters in those drawings to drafting error. As a result, in their view (as well as that of Medline’s counsel), the only illustrations of “catheter assemblies” in the specifications that actually include catheters depict only Foley catheters.

The Court finds this contention unconvincing. Medline’s own expert witnesses agreed upon cross-examination that a catheter is generally understood to be a hollow tube that goes into a human body. *See* Hr’g 1 Tr. at 120–21 (Meyst); *id.* at 83–85 (Weintraub). And they agreed that a hollow tube is displayed as part of the catheter assembly in Figures, 7, 8 and 10. *Id.* What is more, Medline has offered no plausible evidence (other than speculation and argument) that the drafters had intended the figures to depict a Foley catheter, but had inadvertently failed to do so. By contrast, Bard’s expert Karl Leinsing persuasively testified that Figures 7, 8, and 10 show a generic representation of a catheter.⁵ *Id.* at 130. And, indeed, Figures 7, 8 and 10

⁴ Of course, even if Medline’s premise were correct, the disclosure of a single embodiment—a Foley catheter—cannot alone limit the claim language. *See, e.g., SuperGuide*, 358 F.3d at 875.

⁵ The Court granted Medline’s motion to supplement the record with testimony from Leinsing in a related case. According to Medline, Leinsing agreed in that case that a long tube that had been removed from a Foley catheter was not a catheter. Pl.’s Mot. Supp. Record at 8, ECF No. 313. Medline claims that this testimony impeaches Leinsing’s testimony that Figures 7, 8 and 10 illustrate a generic representation of a catheter (rather than no catheter

disclose a catheter assembly that appears to include a drainage bag, which is connected to a short piece of tubing, which is connected to a long hollow tube. As such, the insistence of Medline's experts that no catheter is displayed at all in Figures 7, 8 and 10 is hard to square with the intrinsic evidence.

Medline's witnesses did their best to explain this away. For example, Weintraub testified that her belief that there was no catheter drawn in Figures 7, 8, and 10 was based on the fact that the hollow tube in the illustrations appeared too wide and too long to enter a human body. *See id.* at 95–96. But the “brief description of the drawings” sections of the specifications contain the following caveat: “Skilled artisans will appreciate that elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale. For example, the dimensions of some of the elements in the figures may be exaggerated relative to other elements to help to improve understanding of embodiments of the present invention.” *See, e.g.,* '786 Patent at 3:23–28. Upon cross-examination, Weintraub testified that she had read this portion of the specification, but provided no explanation as to how this

at all as Medline contends). *Id.* This is incorrect. The parties agree that a catheter assembly has a catheter and tubing connected to a catheter. Here, the witnesses agreed that a catheter is, in its simplest form, a hollow tube that goes into the human body. Given that Figures 7, 8, and 10 undisputedly have no Foley catheter drawn, yet depict a catheter assembly with a hollow tube, Leinsing testified that the hollow tube must have been a generic representation of a catheter. By contrast, Medline cites to testimony in which Leinsing, unsurprisingly, testified that a catheter assembly's tube, *removed from a Foley catheter*, was not itself a catheter. *See* Pl.'s Mot. Supp. Record at 8. The Court does not find this testimony to be inconsistent.

language reconciles with her reliance upon the relative dimensions of the illustrated items. *See* Hr’g 1 Tr. at 95–96.

More broadly, the Court finds Weintraub’s testimony that only a Foley catheter is depicted in the patents not convincing and deserving of little probative weight.⁶ Upon cross-examination, Weintraub demonstrated limited experience with non-Foley catheters and with non-urinary catheters. For example, Weintraub testified that her conclusion had been supported by an assumption that intermittent urinary catheters would not be pre-connected to drainage bags, because she had never seen one. Hr’g 1 Tr. at 96–98. But Weintraub admitted that she was shown such a device at her deposition and that her opinion based on her previous knowledge was incorrect. *Id.* Moreover, Weintraub admitted that a rectal balloon catheter may have many of the same elements described in the specification, which she had previously stated were unique to a Foley catheter. *Id.* at 99–100.

Similarly, Meyst testified that he had not been aware that some intermittent catheters came pre-connected to a drainage bag, and his conclusion that the patents depict only Foley catheters was based, at least in part, on an erroneous assumption to the contrary. *Id.* at 122–23. Meyst also testified that he relied on Weintraub’s testimony to confirm his own conclusion. *Id.* at 117–18. Accordingly, the Court also accords Meyst’s testimony little probative weight as to this issue.

⁶ In opposing Weintraub’s testimony on this point, Bard disputes whether Weintraub is a person with ordinary skill in the relevant art. The Court does not reach the issue because, even if she were, Weintraub’s testimony was not persuasive.

For all of these reasons, the Court concludes that a person having ordinary skill in the art would understand that a “catheter assembly” need not include a Foley catheter.

B. “Coiled” Tubing

The parties also dispute whether the tubing component must be “coiled.” Beginning with the claims, the language coming closest to referring to the tubing’s configuration is that the catheter assembly must be “disposed” within the tray. *See, e.g.,* ’935 Patent at 10:20; ’190 Patent at 21:28. The abstract of each patent’s specification is more specific, stating that the claimed invention is “[a] tray for accommodating a coiled medical device, such as a catheter assembly”

Moreover, in each of the patents, the background section of the specification refers to a “long, flexible medical implement,” ’935 Patent at 1:15, and states that “catheter assemblies . . . [are] generally shipped in a coiled configuration,” *id.* at 1:31-33; if the assembly is “inadvertently bent . . . it may no longer be suitable for use,” *id.* at 1:35-37; and the catheter tray is an “improved container for flexible medical devices,” *id.* at 1:57-58. And, in every figure in which a catheter assembly appears, it is displayed in a coiled configuration.

Citing to these references in the specification, Medline contends that the *tubing component* of the catheter assembly must be coiled. But, as we have seen, this is not quite right. Rather, the specification consistently refers to the catheter assembly overall—not the tubing component alone—as being coiled. And, as discussed above, Figures 7, 8, and 10 depict a coiled catheter and a straight tubing

component which, together, created a coiled catheter assembly. *See also* Hr’g 1 Tr. at 129–130 (Leinsing).⁷ These figures are thus inconsistent with Medline’s proposed construction that only the tubing component of the catheter assembly is coiled.

To the extent that Bard contends that no coiling at all is required in the catheter assembly, this too is incorrect. The claim language requires that the catheter assembly must somehow be “disposed” within the catheter package assembly. Furthermore, the specification discloses that this disposal must be in a coiled configuration. For instance, the abstracts state that a catheter assembly is a “coiled medical device”; numerous other references in the written specifications indicate that the catheter assembly is a coiled medical device; and every figure that shows a catheter assembly shows it as coiled. Although mindful that a particular embodiment generally may not be read to limit the scope of a claim, having considered the claim language and the specification in its entirety, the Court concludes that a person having ordinary skill in the art would understand that a catheter assembly is, within the context of the patents-in-suit, a “coiled medical device that includes a catheter connected via tubing to a drainage receptacle.”

II. “Catheter package assembly”

The phrase “catheter package assembly” appears in claim 1 of the ’786 patent and claims 1 through 5, 12, 13, and 15 of the ’190 patent. Medline argues that this

⁷ Once again the extrinsic evidence comports with the intrinsic evidence. Leinsing testified that Figure 7 depicts a coiled generic catheter attached to a short straight tube, which in turn was connected to a drainage receptacle. *Id.* The Court finds this portion of Leinsing’s testimony quite credible, particularly in light of the specification language that “elements in the figures . . . have not necessarily been drawn to scale.” *See, e.g.,* ’786 Patent at 3:23-28.

means “an assembly including a tray, a catheter assembly within the tray, one or more layers of wrap, and a sealed bag.” Pl.’s Br. at 10. Bard contends that no construction is necessary because the claims already define the term. Def.’s Reply at 11–12, ECF No. 282. Medline does not dispute this contention, but nonetheless seeks a construction because jurors will be confused in thinking that a “catheter package assembly” is the same as a “catheter assembly.” Pl.’s Br. at 15.

But Medline does not explain why a jury would confuse these distinct terms. Nor does it elucidate why its proposed paraphrasing of the claim language would alleviate any such confusion. “Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy.” *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). Because there does not appear to be a meaningful dispute about what “catheter package assembly” means, the Court will not further construe the term.

III. “Instruction manual”

The term “instruction manual” appears in claims 1 through 3 of the ’786 patent and claims 1 and 16 of the ’190 patent. Medline proposes that the term means “a booklet of instructions regarding catheterization.” In its brief, Bard argues that an instruction manual is “instructions regarding the use or operation of a product.” As such, the parties disagree as to the subject matter of the “instruction manual” and its physical form.

A. Subject Matter of the Instructions

Medline objects to Bard's proposed construction on the basis that "the use or operation" of the device would, in its view, exclude instructions addressing matters of concern to a health care services provider or patient during the period before and after the catheterization. Bard objects that "catheterization" is too narrow for the same reason. As such, the parties essentially agree on the quintessence of a meaning, but disagree on what words best encapsulate that meaning. *See Markman* Hr'g 2 Tr. ("Hr'g 2 Tr.") at 5–8, ECF No. 312 ("[T]he parties have come together a lot.").

At the *Markman* hearing, the parties agreed that the instructions broadly regard matters of concern to a health care services provider or to a patient. They also agreed that the matters of concern relate to and arise before, during, or after, the use of the catheter assembly. *See id.* This is consistent with the claim language and specifications of the '786 and '190 patents. Accordingly, the Court finds that the "instruction manual" addresses "matters of concern to a health care services provider or to a patient, which relate to and arise before, during, or after, the use of the catheter assembly."

B. Meaning of "Manual"

The crux of the parties' remaining dispute is the meaning of "manual" within the context of the patents-in-suit. Medline contends that every embodiment is a "thin book" and that the dictionary definitions of "manual" and "booklet" both include a thin book. For its part, Bard argues that defining a manual as a "thin book" or

“booklet” adds no clarity to “manual” and is not broad enough to encompass several of the disclosed embodiments.

In the ’786 patent, the instruction manual is illustrated in a number of arrangements. In Figure 14, the manual is displayed as a “step by step guide” that requires page-turning, as with a book. Figure 20 illustrates a single page that is folded “accordion-style” into three parts, and Figure 21 notes that the “patient portion” of instructions is “detach[able].” Another example, Figure 29, illustrates that the instructional manual may include one or more rectangular sheets. In Figures 12 and 13, the manual appears as a single sheet, with detachable portions. And Figures 38 and 39 describe an instruction manual that includes peelable flaps to reveal instructions or that may be in a “[g]reeting [c]ard [f]ormat.”

At the *Markman* hearing, the parties disputed whether a greeting card configuration or a folded single sheet of paper could be considered a “thin book” at all. Hr’g 2 Tr. at 10–13. As such, Medline’s proposal to substitute “booklet” as a synonym for “manual,” on the assumption that both mean “thin book,” adds nothing to resolve the parties’ dispute. And Bard’s proposed construction is too broad; construing “instruction manual” as merely “instructions” (or “printed instructions”) suggests that the “instruction manual” need not be provided in a standalone form, but could for example, be printed on the catheter tray. Such a broad construction is inconsistent with the specifications and the claim language.

At bottom, each of the various embodiments disclosed in the ’786 and ’190 patents describes some type of arrangement of one or more pages of instructions

regarding catheterization. As such, the Court concludes that a person having ordinary skill in the art would understand the physical form of “instruction manual” to be “an arrangement of one or more pages of instructions.” Taken together, the Court adopts the following construction of “instructional manual”: “An arrangement of one or more pages of instructions addressing matters of concern to a health care services provider or to a patient, which relate to and arise before, during, or after, the use of the catheter assembly.”

IV. “Enclosing printed instructions”

The phrase “enclosing printed instructions” appears in claims 1, 17, and 19 of the ’935 patent. Bard contends that this means that the “printed instructions are placed inside the packaged catheter assembly,” while Medline argues that no construction is necessary “because the language of the claims is clear.” Pl.’s Br. at 17. But, while Bard believes that the claim language requires the printed instructions to be placed “inside” the catheter package assembly, Medline has a different view. *Id.* at 21–23. Given this, the Court will construe the disputed language. *See O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361–63 (Fed. Cir. 2008) (stating that a court should construe claim terms when a determination that the term needs no construction would not resolve the parties’ dispute).

After considering the entirety of the language in claims 1, 17 and 19 of the ’935 patent, the Court concludes that Bard’s interpretation is correct. Medline’s primary argument is that the specifications disclose an embodiment that requires a broader

construction. Namely, Medline points to an embodiment where the printed instructions are printed on the CSR wrap and the sterile wrap is optional. *See* '935 Patent at 9:15-21. But the term in dispute is “enclosing printed instructions” as it appears in claims 1, 17, and 19. And each of those claims requires the “placing of sterile wrap about the tray.” *Id.*, 10:26; 11:37; 11:57. To the extent that the embodiment Medline cites is one in which the use of a sterile wrap is optional, it must be directed to other claims in the patent, such as claim 21. “It is often the case that different claims are directed to and cover different disclosed embodiments.” *See Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008).

In any event, to read the embodiment Medline cites into claims 1, 17, and 19 would ignore the language of the claims themselves, which the Court cannot do. *See Tex. Instruments Inc., v. U.S. Int’l Trade Comm’n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (refusing to “construe the claims in the manner [that] would read an express limitation out of the claims” because “[c]ourts can neither broaden nor narrow claims to give the patentee something different than what he has set forth”) (quoting *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 396 (Ct. Cl. 1967)) (internal quotation marks omitted))).

Medline also cites to a number of other embodiments to support its argument. *See* Pl.’s Br. at 17 (citing to '935 Patent at 8:52-55 and 9:11-13). But these embodiments describe a catheter tray assembly with a sterile wrap, within which the instructions (whether affixed to the tray itself or provided therein) are placed. *See*

'935 Patent at 8:44 (referring to Figure 10, which includes a sterile wrap); 9:11-12 (noting that the “assembly can be sealed in a sterile wrap”).

Lastly, Medline cites to the '786 patent, which discloses at least one embodiment with instructions printed on the outside of the sealed bag. Pl.'s Br. at 17–18; '786 Patent at 18:50–60. However, the term “enclosing printed instructions” does not appear in the '786 patent, and so it is not surprising that the specification would disclose an embodiment where the printed instructions appear on, rather than inside, the sealed bag.

Based on the plain meaning of the claim language, as supported by the specifications, the Court construes “enclosing printed instructions” to mean “enclosing printed instructions inside the catheter package assembly.”

V. “Accessing an instruction manual”

The phrase “accessing an instruction manual” appears in claim 1 of the '736 patent and claim 1 of the '190 patent. Bard contends that this means “making use of an instruction manual,” while Medline argues that no construction is necessary because the plain meaning of “accessing” means removing the instruction manual. Here, too, the parties dispute the meaning of the phrase, although they do agree that the meaning of the phrase is the same in both patents.

The term “accessing an instruction manual” is one of several steps in the claims. In the '786 patent, the preceding step discloses “opening a thermally sealed bag disposed about a tray having a catheter assembly disposed therein,” while another step involves the “unfolding one or more layers of wrap to reveal an

additional layer of wrap and the catheter assembly.” ’786 Patent at 26:60–67. Viewed in this context, it appears that “accessing” the instruction manual means merely removing it from the catheter package assembly.

The claim language of the ’190 patent is consistent with this reading. There, the claim requires, among other things, “unfolding the one or more layers of wrap to create a sterile field about the tray” and “accessing an instruction manual comprising a health care services portion and a patient portion detachably coupled thereto.” ’190 Patent at 21:35-39. Thereupon, “detaching the patient portion from the health care services portion; and delivering the patient portion to the patient.” *Id.* at 21:40-42.

Further, the specifications of both patents disclose that “[a]t step 2102, the health care services provider accesses the printed instructions (1001) and begins to read the panels,” ’786 Patent at 25:21–22; ’190 Patent at 19:35–37. And, in both patents, Figure 21—which is described as an illustration of a “method 2100 of using the printed instructions (1001) as described herein,” ’190 Patent at 19:12–14; ’786 Patent at 25:9–11—shows the “Access Instruction Manual” step occurring after “Open Sterile Wrap” and before “Open or Unfold CSR Wrap”; “Set Up Clean Workspace”; “Prepare Catheter”; “Insert Catheter”; “Secure Bag”; and “Detach Patient Portion, Discuss, Give to Patient.”

In light of the intrinsic evidence, Bard’s proposed construction that “accessing” means “making use of” has several deficiencies. First, Bard’s reliance upon a dictionary definition of “access” is misplaced. Rather than limiting the definition of “access” to the “making use of something,” the dictionary definition Bard cites defines

“access” as the “freedom or ability to obtain *or* make use of something.” These are two quite different things.

Bard’s analysis of the intrinsic evidence also falls short. In essence, Bard posits that “accessing” the printed instructions must include “making use” of them, which of course requires the reading of them. But “accessing” the instructions and “reading” them are described as separate actions in the specification. *See* ’768 Patent at 15:21-22 (“the health care provider accesses the printed instructions and begins to read the panels”). And, as we know, “the same claim term in the same patent or related patents carries the same construed meaning” unless otherwise compelled. *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003) (internal citations omitted). Accordingly, the Court agrees with Medline that “accessing an instruction manual” must mean something different than “reading” it or “making use” of it.

As to the file history, Bard points to Medline’s statements during the *inter partes* review (“IPR”). In arguing that “accessing an instruction manual” should be given patentable weight, Medline stated that the phrase goes “well beyond merely informing the patient, and, in fact, transforms the process of using the catheter package assembly. Even [Bard] does not dispute the importance of providing instructions to the patient, and to the order in which certain steps in the catheterization process are conducted.” Def.’s Ex. F, Patent Owner’s Preliminary Response Under 37 C.F.R. § 42.107 at 41. Bard contends that these statements show that the “accessing” step involves using—not just removing—the instructions.

As a preliminary matter, the Court notes that the statements made by Medline in the IPR are not as unequivocal or far-reaching as Bard portrays. But to the extent Medline’s statements suggest that “accessing” involves more than removing the instructions from the catheter package assembly, this is inconsistent with the limitations in the claim language as informed by the specification, and Medline’s statements in the IPR cannot broaden them. *See Helmsderfer*, 527 F.3d at 1383–84; *Tex. Instruments*, 988 F.2d at 1171.

For these reasons, the Court construes “accessing an instruction manual” to mean “removing the instruction manual from the catheter package assembly.”

VI. “A first compartment base member having [at least one/an] inclined, stair-step[ped] contour”

The term “a first compartment base member having [at least one/an] inclined, stair-step[ped] contour” appears, in slightly differing forms, in claims 1, 17, 19, and 22 of the ’935 patent. The parties agree that the term has the same meaning in each claim. Bard argues that the term means “the bottom surface of the first compartment is slanted and adjacent portions of the bottom surface are provided at different heights.” Def.’s Br. at 20. Medline contends that the phrase has a plain and ordinary meaning requiring no further construction and, in the alternative, that it means “the base of the first compartment has at least one incline and has surfaces at different heights.” Pl.’s Br. at 18.

The specification discloses that, in one embodiment, “the first compartment base member 107 includes a stair-stepped contour 115 suitable for accommodating a plurality of syringes at different heights. For example, a first step portion of the stair-

stepped contour 115 may be at a different height within the tray 100 than a second step portion 117 of the stair-stepped contour.” ’935 Patent at 4:60–66. In Figure 4, the “stair-stepped contour” 115 is illustrated as two adjacent portions (116 and 117) provided at different heights. When the same embodiment is viewed from the side in Figure 5, it becomes apparent to a person having ordinary skill in the art that both these portions are inclined. And, although the details are difficult to see, drawings of the tray in other figures, including Figures 7, 8, 9, and 10, all appear to be consistent with Figure 4.

Additionally, the specification would indicate to a person with ordinary skill in the art that the “base members” 107, 108, and 109, are the bottom surfaces of each of the three compartments, which is opposite the top of the tray when the tray is opened from the top. In the illustrated embodiments, the “compartments are open” storage spaces, the spaces’ “top[s] being opposite the base members of the tray” and “bounded on the bottom by a first base member 107, a second base member 108, and a third base member 109.” ’935 Patent at 4:10–14. Moreover, in Figures 1 through 3 and 6 through 8, elements 107, 108, and 109 sit atop the bottom surfaces of the respective compartments. And in Figure 5, 107 designates a point on an inclined portion of the bottom surface of the first compartment, while 108 designates the bottom surface of the second compartment. Because the bottom surface of the second compartment is not inclined, 108 is at a lower height than the bottom surface 107 of the first compartment.

Based on the intrinsic evidence, the Court concludes that a person having ordinary skill in the art would understand the phrase “a first compartment base member having [at least one/an] inclined, stair-step[ped] contour” to mean “the bottom surface of the first compartment, which is opposite the top of the tray when the tray is opened from the top, having at least two adjacent portions provided at different heights, where each portion has an inclined portion.”

Medline seems concerned that the use of the word “bottom” may confuse a reader because, for example in Figure 4, the bottom of the first step portion may not be the “lowest point” (to use Medline’s terminology) of the first compartment. But the Court’s construction expressly limits the bottom surface to be the one “opposite the top of the tray when the tray is opened from the top.” In other words, it is the lowest point of the tray when viewed from the inside of the tray. Medline also argues that “stair-step[ped] contour” does not necessarily mean that the two portions of the bottom surface that are of different heights are adjacent. But the Court agrees with Bard that the plain meaning of “stair-step[ped]” denotes two surfaces of different heights that are adjacent to one another.

For its part, Bard contends that “the bottom of the first compartment is slanted.” However, the claim language uses the inclusive “having,” and Figure 5 illustrates a first compartment in which the left-side portion of the base surface is flat but has an inclined, stair-stepped portion beginning around one-fifth of the way in. This would indicate to a person with ordinary skill in the art that the first

compartment's bottom surface *includes* an inclined, stair-stepped contour, not that the bottom surface must be inclined entirely.⁸

For these reasons, the Court construes “a first compartment base member having [at least one/an] inclined, stair-step[ped] contour” to mean “the bottom surface of the first compartment, which is opposite the top of the tray when the tray is opened from the top, having at least two adjacent portions provided at different heights, where each portion has an inclined portion.”

Conclusion

For the foregoing reasons, the disputed claim terms in the '786, '935, and '190 Patents are construed as set forth in this Memorandum Opinion and Order and Appendix I.

IT IS SO ORDERED

ENTERED: 1/11/19



JOHN Z. LEE
United States District Judge

⁸ Bard also argues that “inclined” should be construed to mean “slanted,” Def.’s Br. at 22, but there does not appear to be any dispute between the parties as to what “inclined” means. As such, no construction of this term is necessary. *See U.S. Surgical Corp.*, 103 F.3d at 1568.

APPENDIX I

Terms as Construed

#	Term	Construction
I	“Catheter assembly”	“A coiled medical device that includes a catheter connected via tubing to a drainage receptacle”
II	“Catheter package assembly”	No construction is required.
III	“Instruction manual”	“An arrangement of one or more pages of instructions regarding matters of concern to a health care services provider or to a patient, which relate to and arise before, during, or after, the use of the catheter assembly”
IV	“Enclosing printed instructions”	“Enclosing printed instructions inside the catheter package assembly”
V	“Accessing an instruction manual”	“Removing the instruction manual from the catheter package assembly”
VI	“A first compartment member having [at least one/an] inclined, stair-step[ped] contour”	“The bottom surface of the first compartment, which is opposite the top of the tray when the tray is opened from the top, having at least two adjacent portions provided at different heights, where each portion has an inclined portion”